IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APICORE US LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
PFIZER INC.,	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

For its Complaint against Defendant Pfizer Inc. ("Pfizer"), Plaintiff Apicore US LLC ("Apicore"), by and through its counsel, alleges as follows:

INTRODUCTION

1. This declaratory judgment action seeking a declaration of non-infringement of United States Patent No. 6,124,363 (the "'363 Patent") to enable Apicore to achieve patent certainty as expressly authorized in the Federal Food Drug and Cosmetic Act ("FDCA") and to bring its generic dofetilide capsules, 0.125mg, 0.25mg, and 0.5mg product ("Apicore's ANDA Product") to market at the earliest possible date to allow the public to enjoy the benefits of generic competitions for these products.

PARTIES

2. Plaintiff Apicore US LLC is a Delaware limited liability company having its principal place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

3. On information and belief, Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 235 East 42nd Street, New York, New York, 10017.

JURISDICTION AND VENUE

4. This is a declaratory judgment action is under the patent laws of the United States, 35 U.S.C. § 1 et seq., the FDCA, 21 U.S.C. § 301 et seq. (as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C § 355)), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. Subject matter jurisdiction is proper under 28 U.S.C. § 1331 and 1338(a).

6. This Court has personal jurisdiction over Pfizer because, among other things, on information and belief, Pfizer is a corporation formed under the laws of the State of Delaware.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

BACKGROUND

FDA Approval of Brand Name and Generic Drugs

8. Under the FDCA, 21 U.S.C. § 301 et seq., an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. 21 U.S.C. § 355(a).

9. The NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §§ 355(b)(1), 355(c)(2)

10. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. 21 U.S.C. § 355(j)(7)(A)(iii).

11. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e).

12. Under the Hatch-Waxman Amendments, a generic manufacturer submits an Abbreviated New Drug Application ("ANDA") and to receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is bioequivalent to the listed reference drug. 21 U.S.C. § 355(j)(2)(A).

13. An ANDA must contain a certification to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the listed reference drug. 21 U.S.C. § 355(j)(2)(A)(vii).

14. An ANDA containing a paragraph IV certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

15. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. 21 U.S.C. § 355(j)(2)(B)(i)-(iii).

16. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

17. The patent holder's filing of a lawsuit prior to the expiration of 45 days prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. 21 U.S.C. § 355(j)(5)(B)(iii).

18. If the patent holder does not file a lawsuit within the 45 days after receiving notice of the ANDA applicant's paragraph IV certification, the applicant's ANDA is to be approved immediately (subject to any 180-day marketing exclusivity). 21 U.S.C. §§ 355(j)(5)(B)(iii), 355(j)(5)(B)(iv)(I).

19. IF the patent holder does not file a lawsuit within the 45 days after receiving notice of the ANDA applicant's paragraph IV certification, the ANDA applicant is permitted to bring a civil action in the form of a declaratory judgment action to obtain patent certainty. 21 U.S.C. § 355(j)(5)(C)(i).

TIKOSYN®

20. Pfizer holds the approved New Drug Application No. 020931 for Tikosyn® (dofetilide capsules).

21. Pfizer sells and distributes a pharmaceutical product under the trade name Tikosyn® that is a dofetilide capsule, 0.125mg, 0.25mg, and 0.5mg.

22. The '363 patent is listed in the Orange Book in connection with NDA No. 020931 and the brand name drug Tikosyn®.

23. Pfizer, as holder of NDA No. 020931, listed or caused to be listed the '363 patent in the Orange Book for NDA No. 020931.

APICORE US LLC'S ANDA

24. Apicore US LLC submitted ANDA No. 208625 to the FDA under section 505(j) of the FDCA, seeking approval for dofetilide capsules, 0.125mg, 0.25mg, and 0.5mg, as defined in ANDA No. 208625 ("Apicore's ANDA Product").

25. Apicore US LLC's ANDA No. 208625 includes a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '363 patent is invalid, unenforceable, and/or will not be infringed by Apicore's ANDA Product.

THE '363 PATENT

26. The '363 patent is entitled "DOFETILIDE POLYMORPHS" and lists Pfizer Inc. on its face as the assignee. The Orange Book lists the '363 patent's expiration date as October 9, 2018.

27. Upon information and belief, Pfizer Inc. owns the right, title, and interest in the '363 patent. A true and correct copy of the '363 patent is attached hereto as Exhibit A.

28. The '363 patent claims three different polymorphs of dofetilide – P162, P162a, and P143. All claims require, *inter alia*, one of those three polymorphs of dofetilide.

29. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apicore sent a letter dated May 18, 2016, (the "Notice Letter") to Pfizer, Inc., stating Apicore had certified the '363 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the new drug for which ANDA No. 208625 is submitted.

30. Apicore's Notice Letter notified Pfizer that Apicore had filed ANDA No. 208625 with the FDA, seeking approval for its dofetilide capsules, 0.125mg, 0.25mg, and 0.5mg, prior to the expiration of the '363 patent.

31. Apicore's Notice Letter notified Pfizer that Apicore's ANDA Product does not contain any of dofetilide polymorphs P162, P162a, and/or P143, and for at least that reason does not infringe any claims of the '363 patent.

32. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc), the Notice Letter contained an Offer of Confidential Access, as defined by 21 U.S.C. § 355(j)(5)(C)(i)(III). Pfizer availed itself

of the Offer of Confidential Access, and was permitted to receive and review Apicore US LLC's ANDA No. 208625.

33. Pfizer declined to bring a civil action against Apicore for infringement of the '363 patent before the expiration of forty-five days after which they received notice that Apicore had submitted ANDA No. 208625 to the FDA seeking approval for dofetilide capsules, 0.125mg, 0.25mg, and 0.5mg, prior to expiration of the '363 patent.

34. A real, actual and justiciable controversy exists between Apicore on the one hand, and Pfizer on the other hand, regarding Apicore's non-infringement of the '363 patent. This actual controversy regarding patent certainty is defined by 21 U.S.C. §355(j)(5)(C)(i) and is within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '363 PATENT

35. Apicore repeats and realleges each of the allegations in paragraphs 1-34 as if fully set forth herein.

36. Apicore does not, and would not if it were to market its ANDA Product, infringe, contribute to the infringement of, or induce the infringement of any valid claim of the '363 patent.

37. Apicore is entitled to a declaration that Apicore's ANDA Product does not infringe, contribute to the infringement of, or induce the infringement of any valid claim of the '363 patent.

PRAYER FOR RELIEF

WHEREFORE, Apicore respectfully requests the Court to enter judgment as follows:

a) ordering that judgment be entered in favor of Apicore US LLC;

b) declaring that the manufacture, use, sale, offer for sale, or importation of the dofetilide capsule that is the subject of ANDA No. 208625 does not infringe, directly or indirectly, either literally or under the doctrine of equivalents, and would not, if marketed, infringe any valid and/or enforceable claim of the '363 patent;

c) declaring this case exceptional and awarding Apicore US LLC its costs, expenses, and attorneys' fees under 35 U.S.C. § 285; and

d) awarding Apicore US LLC such other and further relief as the Court may deem just and proper.

Dated: December 12, 2016

/s/ Kenneth L. Dorsney

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